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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,060	11/07/2005	Andreas Meinke	SONN:080US	5339

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EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	**PAPER NUMBER**
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/556,060	MEINKE ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-61* is/are pending in the application.

4a) Of the above claim(s) *51-52 and 55-60* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-50,53,54 and 61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed on 5/14/07 is acknowledged.

Status of claims

2. Claims 38-44 have been canceled.

Claim 45 has been amended.

New claim 61 has been added. No new matter was added by these amendments.

Claims 45-61 are pending in the application.

Claims 45-50 , 53-54 and 61 are under examination.

Claims 51-52 and 55-60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group of inventions.

Claim Rejections - 35 USC 101 withdrawn

3. In view of amendment to the claims , the rejection under 35 U.S.C. 101 is withdrawn.

Claim Rejections - 35 USC 112, first paragraph maintained

4. The written rejection of claims 45-50 , 53-54 and 61 under 35 U.5.C. 112, first paragraph is maintained for the same reasons as set forth in the action mailed on 12/13/06, section 8, pages 5-9 . Applicant states that the method by which relevant antigens, such as SEQ ID NO: 364, are identified using sera from individuals with antibodies against S.*agalactiae and* is disclosed in Specification, p. 4, last paragraph, to page 5, third paragraph; and Example 1. Further "an immunogenic fragment of SEQ ID NO: 364 comprising one or more of amino acid sequences 414-420, 427-437, 455-475,494-510, 386-458 or 458-624 of SEQ ID NO:364 have been shown in Table 1A on page 77, these specific sequences identify the locations of identified immunogenic regions and predicted immunogenic amino acids of SEQ ID NO:364.

The arguments have been considered but has not been found persuasive because the specification specifically teaches at table 1a that these sequences are "predicted" to be immunogenic and the art recognizes that unpredictability of the immunogenicity of linear peptides . In particular, it is unpredictable that sequences that are specific for SEQ ID NO:364 are exposed on the surface of SEQ ID NO:364 (text book, Roitt et al, 1998, Immunology, 4th ed, Mosby, London teach that although it is possible to produce antibodies to almost any part of an antigen, this does not normally happen in an immune response. It is usually found that only a certain areas of the antigen are particularly antigenic, and that a majority of antibodies bind to these regions. These regions are often at exposed areas on the outside of the antigen, particularly where there are loops of polypeptide that lack a rigid tertiary structure (p.7.7-7.8). However, the specification fails to disclose sufficient guidance and objective evidence as to the linear and or three-dimensional conformation of the polypeptide fragments which constitute epitopes

recognized by the claimed invention. Antibodies bind to structural shapes that may be linear stretches of amino acids, conformational determinants formed by the folding of peptides, carbohydrate moieties, phosphate or lipid residues or a combination thereof. Therefore, "the issue remains the same . Further, the claims are not limited to the specifically recited sequences since the claims still recite an isolated hyperimmune serum-reactive antigen comprising an immunogenic fragment of SEQ ID NO:364 or comprising one or more of amino acid sequences 414-420, 427-437, 455-475,494-510, 386-458 or 458-624 of SEQ ID NO: 364and for the reasons of record, the specification does not provide a written description of the claimed invention. further," specification discloses putative immunogenic fragments consisting of amino acid sequences 414-420, 427-437, 455-475,494-510, 386-458 or 458-624 of SEQ ID NO:364 (fragments of 25-30 amino acids), however, the claims as currently constituted are drawn to immunogenic fragment of SEQ ID NO: 364 comprising one or more of amino acid sequences 414-420, 427-437, 455-475,494-510, 386-458,or 458-624 of SEQ ID NO:364 and the specification fails to provide a written description of any fragment that will function as claimed, that is in a pharmaceutical composition . Thus, immunogenic polypeptide as claimed are broader than SEQ.ID.NO: 364 and read on variety of genus fragments. Further, it is noted that that although applicant argues that the claimed invention is required to be immunogenic , it is noted for applicant's information that immunogenicity/immunoreactivity is not considered to be a function of the polypeptide, rather, it is a physical property of the polypeptide. A physical property is a basic or essential attribute shared by all members of class as defined by http://dict.die.net/property. Or a property used to characterize physical objects as defined by http://wordnet.princeton.edu/perl/webwn. In the instant case, the basic or essential attribute shared by all members of the claimed class, the property used to characterize these molecules is the physical property of a particular epitope on the polypeptides. In point of fact, the only molecule that has a function drawn to the immunogenicity of a polypeptide , is the immune system molecule that binds to it. Thus , as previously set forth, the specification provides no nexus between any structure and function of the broadly claimed fragments. This is especially true given that immunogenicity is not a function of the claimed polypeptide. Although the specification states that the claimed molecules are part of the invention and make reference to a potential method for making it. This does not satisfy the requirements as previously set forth. Therefore, the rejection is maintained.

5. The scope of enablement rejection of claims 45-50 , 53-54 and 61 under 35 U.5.C. 112, first paragraph is maintained for the same reasons in the Office action mailed on 12/13/06, section 9, pages 9-13.

Applicant states that hyperimmune serum reactive antigen comprising an immunogenic fragment of SEQ ID NO: 364 comprising one or more of amino acid sequences 414-420, 427-437, 455-475, 494-510, 386-458, or 458-624 of SEQ ID NO:364 was capable of eliciting an immune response would not require undue experimentation because it could be accomplished by routine screening using methods such as those described in Example 4 in the present specification .

The arguments have been considered but has not been found persuasive because the court found in Rochester v. Searle, 358 F.3d 916, Fed Cir., 2004 that screening assays are not sufficient to enable an invention since they are merely a wish or plan for obtaining the claimed chemical invention. while methods for screening immunogenic fragments are known and could be accomplished by routine screening but pharmaceutical composition comprising immunogenic fragment of SEQ ID NO: 364 comprising one or more of amino acid sequences 414-420, 427-437, 455-475, 494-510, 386-458, or 458-624 of SEQ ID NO:364 require undue experimentation as the specification does not teach fragments of sequences 414-420, 427-437, 455-475, 494-510, 386-458, or 458-624 can be used in a pharmaceutical composition, especially a vaccine for preventing infection by S. agalactiae .

Applicant provided the declaration of Dr. Senn (the Senn Declaration) as further evidence of the enablement of the current claims. The Senn Declaration describes both active and passive immunizations studies using an isolated hyperimmune serum-reactive antigen encompassed by the current claims. Dr. Senn is the Head of Infectious Disease Models at Intercell AG, which is the assignee of the present application. The gbs2018 antigen used in these studies corresponds to amino acids 36 to 612 of SEQ ID NO: 364 (Senn Declaration, para. 3).

The Office carefully gone through the declaration and understands that the gbs2018 antigen used in these studies corresponds to amino acids 36 to 612 of SEQ ID NO: 364 which is a contiguous amino acid sequence. However, the claimed invention is drawn to fragments less than 20 amino acids and the declaration does not provide evidence that these fragments induce protective immune response required by the current claims. Therefore, the declaration is not sufficient to overcome the rejection.

Claim Rejections - 35 USC 102 maintained

6. The rejection of claims 45-49 and 53-54 under 35 U.S.C. 102(b) as being anticipated by Telford et al Accession number ABP28545, publication number WO 200234771-A2 is maintained for the same reasons in the Office action mailed on 12/13/06, section 13, pages 14-15. Applicant states that Telford does not disclose SEQ ID NO:364 or the fragments of SEQ ID NO:364 recited in the current claim.

The arguments have been considered but has not been found persuasive because the claims are not limited to SEQ ID NO:364 or the specifically recited fragments but are drawn to an amino acid sequence of SEQ ID NO:364 or immunogenic fragments of SEQ ID NO:364.

7. The rejection of claims 45-49, 53-54 and 61 under 35 U.S.C. 102(b) as being anticipated by Glaser et al Accession number ADV88412 and publication number FR 2824074 is maintained for the same reasons in the Office action mailed on 12/13/06, section 14, pages 15-16.
Applicant states that Glaser does not anticipate the current claims because Glaser does not teach a pharmaceutical composition comprising an isolated hyperimmune serum-reactive antigen

comprising an amino acid sequence of SEQ ID NO: 364 or an immunogenic fragment of SEQ ID NO: 364 comprising one or more of amino acid sequences 414-420, 427-437, 455-475,494-510 etc.

The arguments have been considered but has not been found persuasive because clearly the art discloses an identical polypeptide, SEQ.ID.NO: 806 comprising 643 amino acid sequence. As peptide with at least 5 –8 amino acids is known to induce an immune response , the polypeptide with 643 amino acid sequence is immunogenic. Therefore, the disclosed composition reads on the pharmaceutical composition as it contains the same structural component and is capable of performing the same use, i.e., pharmaceutical composition. Therefore, the rejection is maintained.

Remarks

8. No claims are allowed.

This application contains claims 51-52 and 55-60 drawn to an invention nonelected A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

10. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600

Padma Baskar Ph.D

SUSAN UNGAR, PH.D
PRIMARY EXAMINER